

## § 493.1467

### **§ 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.**

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of § 493.1469 of this subpart, and provides supervision in accordance with § 493.1471 of this subpart.

### **§ 493.1469 Standard: Cytology general supervisor qualifications.**

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

- (a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or
- (b)(1) Be qualified as a cytotechnologist under § 493.1483; and
- (2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

### **§ 493.1471 Standard: Cytology general supervisor responsibilities.**

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The cytology general supervisor must—

- (1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;
- (2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under § 493.1274(c));
- (3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

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- (4) Document the number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

### **§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.**

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

### **§ 493.1483 Standard: Cytotechnologist qualifications.**

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1994, have full-time experience of at least 2 years

or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—

- (i) Graduated from high school;
  - (ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and
  - (iii) Completed 2 years of full-time supervised experience in cytotechnology; or
- (5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and
- (ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

**§ 493.1485 Standard; Cytotechnologist responsibilities.**

The cytotechnologist is responsible for documenting—

- (a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in § 493.1274(c));
- (b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and
- (c) The number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

**§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.**

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

**§ 493.1489 Standard; Testing personnel qualifications.**

Each individual performing high complexity testing must—

- (a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and
- (b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(1) 24 semester hours of medical laboratory technology courses; or

(2) 24 semester hours of science courses that include—

- (i) Six semester hours of chemistry;
- (ii) Six semester hours of biology; and
- (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(3) Have previously qualified or could have qualified as a technologist under § 493.1491 on or before February 28, 1992;